

Exhibit E

Christina K. Pramudji, M.D.

1 IN THE UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF WEST VIRGINIA
2 CHARLESTON DIVISION
- - -

3
IN RE: ETHICON, INC., PELVIC : MASTER FILE NO.
4 REPAIR SYSTEM PRODUCTS :: 2:12-MD-02327
LIABILITY LITIGATION :
5 : NO. 2327
6 THIS DOCUMENT RELATES TO: : CASE NO.
DIANNE M. BELLEW, :: 2:13-CV-22473

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9
September 17, 2014

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12 Videotaped deposition of CHRISTINA K. PRAMUDJI,
13 M.D., taken pursuant to notice, was held at the Westin
14 Galleria, 5060 West Alabama, Street, Houston, Texas, beginning
15 at 10:24 a.m., on the above date, before Mary Kay Hendricks,
16 CSR, a Registered Professional Reporter, Certified Shorthand
17 Reporter.

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1 A. No, I wouldn't say that I would hold myself out
2 as a design expert.

3 Q. You do not hold yourself out as a regulatory
4 expert, correct?

5 A. That's correct.

6 Q. You do not hold yourself out as having any
7 expertise or knowledge regarding what FDA regulations
8 require to be included in the warnings and information
9 provided by a medical device manufacturer for a product
10 like the Prolift, do you?

11 MR. SNELL: Form.

12 A. I know kind of what happened with Prolift, but
13 I -- I would not say I'm an expert in that, no.

14 Q. (BY MR. SLATER) When you say you know what
15 happened with Prolift, are you talking about the fact
16 that it was withdrawn from the market?

17 A. No, no.

18 MR. SNELL: Form.

19 A. I'm talking about the -- the fact that they
20 followed the pathway for approval rather than going for
21 the 510(k).

22 Q. (BY MR. SLATER) I didn't ask about that
23 though. You realize that wasn't my question, right?

24 A. That's how I interpreted your question.

25 Q. You're not familiar with the regulations from

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1 the FDA that specify what type of information is
2 supposed to be found in warnings for the products like
3 the Prolift, correct?

4 MR. SNELL: Form.

5 A. No, I'm not.

6 Q. (BY MR. SLATER) You're not familiar with the
7 internal standards at Ethicon that the medical affairs
8 and regulatory affairs people followed in terms of what
9 information needed to be in the IFU and the patient
10 brochure and other documents about the Prolift, correct?

11 A. That's correct. I don't know that.

12 Q. In drawing (sic) your opinions, you did not
13 rely on any internal standards or any deposition
14 testimony by any Ethicon witness as to what information
15 needed to be in the IFU, the patient brochure or any
16 other document about the Prolift, correct?

17 MR. SNELL: Form.

18 A. I don't -- I don't believe I did, not that I
19 can recall off the top of my head, no.

20 Q. (BY MR. SLATER) You do not know what the
21 requirements were that Ethicon had to satisfy before
22 they could market the Prolift, do you?

23 A. No, I don't.

24 Q. You do not know what was considered by the
25 Ethicon medical affairs director at the time that she

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1 signed off to allow the Prolift to be marketed, do you?

2 A. No, I don't.

3 Q. You do not know what information was available
4 to the Ethicon medical affairs director at the time that
5 she signed off to allow the Prolift to be marketed, do
6 you?

7 A. No, I don't.

8 Q. You do not know what information -- well, do
9 you know what a DDSA or an FMEA is?

10 A. No clue.

11 Q. You don't know anything about the design
12 control process where the DDSA and FMEAs were conducted,
13 do you?

14 A. No.

15 Q. You know nothing about the risk assessment
16 process and the post-market surveillance process at
17 Ethicon regarding the Prolift, correct?

18 MR. SNELL: Form.

19 A. I know that they track phone calls coming in
20 from physicians and patients, et cetera, but beyond that
21 I don't -- I don't have any other detailed knowledge.

22 Q. (BY MR. SLATER) You have no information as to
23 what type of information was provided to Ethicon
24 specifically regarding the Prolift once the Prolift went
25 on the market, correct?

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1 A. I know that physicians would call in and
2 patients would call in, but I'm not sure what you're
3 referring to beyond that.

4 Q. You know that Ethicon would receive information
5 about the Prolift from doctors and patients and others,
6 but you have no specifics about what that information
7 was, correct?

8 A. I mean, I've seen a few things, but -- I mean,
9 not -- I don't have the whole body of that, no. I
10 don't -- that would be beyond what I'm doing here.

11 Q. Did you ask the attorneys who retained you to
12 make sure you had any documents that demonstrated
13 Ethicon's knowledge as to severe or catastrophic
14 complications with the Prolift? Did you ask to see that
15 so you'd have a full picture of what Ethicon knew about
16 the most serious complications?

17 MR. SNELL: Form.

18 A. No, I did not.

19 Q. (BY MR. SLATER) Did you make any effort to
20 learn that information?

21 A. No, I did not.

22 Q. In drawing your opinions, did you assume that
23 if Ethicon knew about a severe complication with --
24 connected with the Prolift that it would have been
25 reported to the FDA?

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1 A. Can you repeat that question, please?

2 Q. Sure. Did you assume that if Ethicon had
3 knowledge of a severe complication occurring with the
4 Prolift that it would have been reported to the FDA?

5 A. I never -- I never really thought about it.

6 Q. You gave no consideration to whether or not
7 Ethicon evaluated or reported complications or reports
8 of complications with the Prolift, correct?

9 A. That's correct.

10 MR. SNELL: Form.

11 Q. (BY MR. SLATER) Is it fair to say your
12 opinions are based upon your own clinical experience and
13 knowledge and are not with regard in any way to what
14 Ethicon knew or what Ethicon specifically did? Is that
15 fair?

16 MR. SNELL: Form.

17 A. Can you repeat that question one more time,
18 please?

19 MR. SLATER: Let the court reporter read it
20 back just to get it the same way.

21 (The requested material
22 was read by the reporter.)

23 A. I'm not sure how to answer that because I -- I
24 mean, I have some information about that, but I don't
25 have -- you know, that wasn't the main focus, but I do

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1 information.

2 Q. (BY MR. SLATER) If you cited an article in
3 your report, did you attempt to be -- I'm going to use
4 the term "fair and balanced" in summarizing the data
5 from the report -- from the study if you actually gave
6 data from the study in your report?

7 A. Yes, I did.

8 Q. Did you feel that was your obligation as an
9 expert to give both sides of the story to the extent
10 both sides are told in an article?

11 A. Yes.

12 Q. If you failed to do so, that would be a failure
13 in being objective, correct?

14 MR. SNELL: Form.

15 A. Yes.

16 Q. (BY MR. SLATER) In forming your opinions as to
17 whether or not the warnings for the Prolift were
18 adequate to communicate the risks and complications, you
19 did not refer to or rely on any specific standard,
20 correct?

21 A. I mean, I relied on general surgical principles
22 and standards.

23 Q. Well, in determining whether or not the IFU for
24 the Prolift adequately warned of the risks and
25 complications, did you base your opinion on your own

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1 judgment and your own evaluation based on your
2 experience?

3 A. Yes.

4 Q. You did not rely on any particular standards,
5 for example, an FDA regulation or any statement by
6 anyone at Ethicon as to what they were supposed to
7 communicate in those warnings, correct?

8 A. Correct.

9 MR. SNELL: Form.

10 Q. (BY MR. SLATER) You could not give me an
11 objective standard that you applied. It was simply --
12 and then I could then apply your same standard. It's
13 simply what you think is right or adequate based on your
14 own experience, right?

15 MR. SNELL: Form.

16 A. Yeah. I would say that's correct.

17 Q. (BY MR. SLATER) Okay. If Ethicon knew of
18 significant risks and complications with the Prolift
19 from their own internal studies or from information they
20 got from other physicians, would you agree they needed
21 to warn of that information in the IFU?

22 A. No, not necessarily.

23 Q. Do you know if Ethicon internally thought that
24 they needed to warn based on the standards that they say
25 that -- rephrase. Do you know whether the standards